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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/020,393	02/09/1998	PETER J. SIMS	OMRF-170	3210

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/020,393	SIMS, PETER J.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 12/2/05 has been entered.
Claims 6, 10 and 11 have been amended.

Claims 1-19 are pending.

Claims 20-35 have been canceled previously.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's arguments, filed 12/2/05.
The rejections of record can be found in the previous Office Action, mailed 9/23/05.

3. Claims 1-3, 5, 6 and 7 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,843,884. Although the conflicting claims are not identical, the are not patentably distinct from each other because the patent claims are drawn to peptides, anti-idiotypic antibodies and cyclized peptides which bind to the same C9 amino acid specificity as claimed in the instant application and thereby anticipate the instant claims.

Applicant's arguments have been fully considered but are not found convincing essentially for the reasons of record.

Applicant asserts that nothing in the claims of the '884 patent points to the particular species of peptidomimetics of CD59 residues 42-58.

However as pointed out previously, the instant claims recite limitations drawn to "peptides", including "cyclized peptides", and "anti-idiotypic antibodies" that appear to have the same or nearly the same structure and function of the human CD59 amino acid residues 42-58 of SEQ ID NO: 3 and which bind the same or nearly the same human C9 amino acids residues as the "molecules" claimed in U.S. Patent No. 5,843,884.
It is noted that the claimed instant CD9 specificity and the patented CD9 specificity are the same sequence, even though the CD9 amino acid specificity is claimed differently.
Further, the '884 claimed molecules modulate binding of CD59 to CD9 consistent with the instant claims drawn to compounds that specifically inhibit the formation of the C5b-9 complex via C9-specific binding.

In contrast to applicant's assertions, including those encompassing the "CD59 residues 42-58",
it appears that the instant claims and the patented claims as currently recited would either anticipate or render obvious each other in the absence of evidence to the contrary. For example, applicant has not provided sufficient objective evidence or provide sufficient information to indicate that the patented "cyclized peptides" and "anti-idiotypic antibodies" anticipate or render obvious the instant claimed "molecules", given common structural and functional limitations.

Again, applicant is invited to distinguish or clarify the differences between the instant claims and the patented claims.

4. Claims 1-2, 7, 10-11 and 16-17 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant's arguments in conjunction with the Sims Declaration, filed 12/5/05, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant relies upon the instant specification's provision that the structure of human CD59 amino acid residues 42-58 of SEQ ID NO: 3 must be faithfully reproduced by the mimetic and that the disclosed discussion how to obtain such mimetics by screening and rational drug adequately provides possession of a large genus of mimetics a the time of filing, including nucleic acids and small molecules.

A pointed out previously, the instant claims encompass "peptidomimetics having the structure and function of human CD59 amino acid residues 42-58 of SEQ ID NO: 3", including "a nucleic acid" and "a small molecule", however there is insufficient written description of such "nucleic acids" and "small molecules" having the structure and function of the claimed "peptidomimetics" in the application as filed.

The instant specification and claims do not provide functional characteristics coupled with a known or disclosed correlation between function and structure as it reads on "nucleic acids" and "small molecules" as "peptidomimetics having the structure and function of human CD59 amino acid residues 42-58 of SEQ ID NO: 3".

For example, page 11 of the instant specification describes "peptidomimetics" that present the surface exposed side chain in amino acids in the same relative positions as those positions of CD59 which bind to active portions of human C9.

"Nucleic acids" and "small molecules" do not share common structural characteristics as "proteins" and "immunoglobulins".

The following precautions against applicant's reliance upon screening and rational drug were raised in University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004) as well as the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001 (also, see MPEP 2163).

Not having "peptidomimetics" particularly "nucleic acid and small molecule peptidomimetics" which have been specifically named or mentioned in a sufficient manner that provides sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics, one is left is selection from the myriad of possibilities encompassed by the broad disclosure with insufficient guides indicating or directing that this particular selection should be made rather than any of the many other which could be made or selected.

One of the many problems with laundry list or shotgun patent disclosures is that while they may lead to numbers games about how many compounds can be disclosed by the use of generic formulas or screening assays, they do little to provide the statutory written description required for patent claims to actual inventions.

Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define by its method of preparation, its physical or chemical properties of whatever characteristics sufficiently distinguish it. It is insufficient to define it solely by its principal biological property because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property

When an inventor is unable to envision the detailed constitution of a "nucleic acid" and "small molecule" so as to distinguish them from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e. until after the compounds have been isolated.

Applicant's, including the Sim's Declaration's statements that given the specification instructions as to the structure that define the claimed compounds places applicant is possession of a wide variety of mimetic compounds, including "nucleic acids" and "small molecules" are conclusory for which there is insufficient supporting objective evidence is provided.

Applicant's assertions do not provide sufficient evidence that the physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics provides possession of "nucleic acids" and "small molecules", given that these "nucleic acids" and "small molecules" do not share common structural characteristics with "proteins" and "immunoglobulins".

See the previous Office Action, mailed 9/23/05, for the rejection of record.

Applicant's arguments have not been found persuasive.

5. Upon reconsideration, the previous rejection under 35 U.S.C. § 112, second paragraph, has been withdrawn.

6. Claims 1 and 10 stands objected to because "anti-ID" should be spelled out as "anti-idiotypic" for clarity.

7. As indicated previously, claims 4, 8, 12-15, 18-19 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, first paragraph, set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims.

8. Applicant's request, filed 12/2/05, for an Interview is acknowledged.

Given administrative procedures for responding to applicant's amendments and that all business with the USPTO is transacted in writing, this Office Action is set forth in response to applicant's amendment, filed 12/6/05.

If applicant desires an Interview, applicant may contact the examiner accordingly.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 17, 2006